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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/966,233	11/07/97	LEE	S 241800

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EXAMINER	
ALLEN, M	
ART UNIT	**PAPER NUMBER**
1631	53

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/966,233	Applicant(s) LEE, SE-JIN	
	Examiner Marianne Allen	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,11-15,22 and 24-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,11-15,22,24-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
18)☐ Interview Summary (PTO-413) Paper No(s). _____.
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Claims 32-38 have been newly introduced.

Response to Arguments

Applicant's arguments filed 4/3/01 have been fully considered but they are not persuasive.

The rejection of claim 31 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to the claim.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

Claims 3, 11-15, 22, and 24-38 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial and credible utility or by a well established utility.

This rejection is maintained for reasons of record as applied to claims 3, 11-15, 22, and 24-31 and newly applied to claims 32-38 for the same reasons.

Claims 3, 22, 24-25, 32, and 35 are directed to isolated DNA segments encoding GDF-1 proteins. Claim 31 is directed to a complementary DNA segment. Claims 11, 26, and 33 are directed to vector containing a DNA segment encoding GDF-1. Claims 12-14, 27-29, and 36 are directed to host cells. Claims 15, 30, 34, and 37 are directed to methods of producing recombinant GDF-1. The protein products lack patentable utility for the reasons set forth below; therefore, the methods of producing the protein and vectors and hosts used therefore (claims 11-15 and 26-30) to make these protein products must also lack patentable utility.

Applicant argues that there are "at least three utilities for GDF-1 that support the claimed invention, any one of which would be adequate to provide a practical utility." The first named utility in the response is use as a specific marker for a tumor arising from a cell type that normally expresses the gene or protein. The examiner notes that no tumors have been identified in the specification as arising from a cell type that normally expresses the GDF-1 gene or protein. Thus, this is not a specific, substantial, and credible utility nor a well-known utility for GDF-1. The second named utility in the response is a marker for a particular cell lineage. Applicant references an abstract to Thibodeau et al. (1989). The examiner notes that GDF-1 has not been demonstrated to be a marker for a particular cell lineage in the specification nor is this use asserted. Thus, this is not a specific, substantial, and credible utility nor a well-known utility for GDF-1. Thibodeau et al. can be distinguished from the instant application at least because it discloses producing monoclonal antibodies and screening them to find monoclonal antibodies with unique patterns of immunoreactivity. Some antibodies found are characterized as regional, cell-lineage, cell-cycle, or extracellular material-associated markers. Again, GDF-1 has not been characterized in the specification as a marker. The third named utility in the response is a cell survival molecule in neuronal culture. The examiner notes that the specification does not positively assert that GDF-1 is a cell survival molecule in neuronal culture. As pointed to by applicant in the response the specification states, "**If** GDF-1 possesses a similar activity…GDF-1 will **likely** prove useful…" (emphasis added). Again, the examiner maintains that the specification clearly discloses that at the time of the invention the specific biological activity associated with GDF-1 was not known. Applicant again proffers the Ebendal declaration. The examiner notes that none of the comments in the prior Office action concerning the deficiencies

of the Ebendal declaration have been addressed. The examiner further notes that the Ebendal declaration does not show that GDF-1 has an activity also known to be possessed by activin at the time of the invention. As such, applicant's arguments on page 7 of the response with respect to activin appear to be misplaced. Thus, use as a cell survival molecule is not a specific, substantial, and credible utility nor a well-known utility for GDF-1.

As set forth in the prior Office action, the specification discloses that the GDF-1 proteins **may** have any of a number of biological activities based upon similarity to members of the TFG-β superfamily. It is noted that these activities vary quite widely. The similarities between particular GDF-1 proteins and the TGF-β family members range from 26-52% on the amino acid level. (See specification page 12, lines 8-20.)

The specification makes clear that further experimentation is necessary to confirm the activity and uses of the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility.

Claim Rejections - 35 USC § 112

Claims 3, 11-15, 22, and 24-38 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

This rejection is maintained for reasons of record as applied to claims 3, 11-15, 22, and 24-31 and newly applied to claims 32-38 for the same reasons.

Claims 3, 11-15, 22, and 24-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is maintained for reasons of record as applied to claims 3, 11-15, 22, and 24-31 and newly applied to claims 32-38 for the same reasons.

Claim 3 is directed to DNA segments encoding mouse or human GDF-1. Claim 22 is directed to mammalian GDF-1 proteins defined in an open reading frame of Figure 2 or Figure 11A or Figure 11B. Claims 24-25 and 35 specifically include sequence outside the open reading frame. Claim 31 is directed to a complementary sequence under certain hybridization conditions. All of the claims use open language.

First of all, the claim language used clearly encompasses the genomic sequences (particularly apparent in claims 24-25 and 31) which have not been disclosed and are thus not described. It is noted that the sequences disclosed were derived from cDNA sequences. With respect to claim 31, it is particularly noted that the Southern blot experiments in Example 5 demonstrate that even under high stringency hybridization conditions, additional bands were detected in addition to a predominant band and their sequence structure is not described. The specification clearly distinguishes them from partial digestion products.

Applicant's response does not address why the structure of the genomic sequences encompassed are described by the specification. Applicant's response does not address what

the expected structure for other members of this family are nor what structural features identify a protein as a GDF-1 protein. Furthermore, as the activity of GDF-1 was not known at the time of the invention, the specification does not enable any assays for identification of GDF-1. Applicant's response does not address this point. As such, none of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 appears to be directed to the same subject matter as claim 24. There does not appear to be any difference in scope between the claims.

Applicant's comments regarding U.S. Patent Nos. 6,008,017 and 6,074,841 are again not germane. The inventors, assignee, and subject matter are not shared by the instant application. The issued claims are not directed to GDF-1. Each application is examined independently and on its own merits.

It is believed that all pertinent arguments have been addressed.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
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